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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,742	10/06/2005	Deborah Addison	JJM0620USPCT	3713

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EXAMINER	
JACKSON, BRANDON LEE	

ART UNIT	PAPER NUMBER
3772	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,742	ADDISON ET AL.	
	Examiner	Art Unit	
	BRANDON JACKSON	3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 5-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2 and 5-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to amendments/arguments filed 4/14/2008. Currently, claims 1-2 and 5-15 are pending in the instant application.

Response to Arguments

Applicant's arguments filed 4/14/2008 have been fully considered but they are not persuasive. Applicant argues the Kirkwood/Heinecke device does not teach water-impermeable envelope, wherein the envelope contains a therapeutic agent and wherein the therapeutic agent is retained inside the envelope after the aperture has opened. However, Kirkwood teaches a water-impermeable (par. 0058) envelope (par. 0061) having an aperture (par. 0011) that is blocked by a degradable material (par. 0014), therefore, allowing the therapeutic agent to be retained inside the envelope when the aperture is open, because the therapeutic agent will not pass through the aperture until exudate contacts the degradable material to dissolve it.

Further, Applicant argues the Heinecke/Arnold device fails to disclose the therapeutic agent is retained inside the envelope after the aperture has opened. However, Heinecke teaches a water-impermeable (col. 5-6, lines 60-7) envelope (19) having one aperture (18) and Arnold teaches a degradable material that block the apertures until it is absorbed by the wound to release the therapeutic agent from behind. Moreover, the Arnold states the therapeutic agent is held in position until exudate contacts the device to being the passage of fluids. Therefore, the therapeutic agent is

retained inside the envelope after the aperture has opened as long as exudate has not contacted the surface of the device.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2 and 5-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kirkwood et al. (U.S. Patent Application Publication 2004/0241214) in view of Heinecke (US Patent 4,499,896). Kirkwood discloses a wound treatment device (1) comprising a water-impermeable (par 0058) envelope (par 0061) made of a flexible sheet (par 0013 and 0015) having at least one aperture (par 0011) that is blocked by a degradable material (par 0014) that breaks down in the presence of exudates (par 0014) thereby permitting therapeutic substances to pass through the apertures to the wound (par 0011). The total area of the apertures is from about 0.01 to 1 cm^2 (par

0018). The degradable material comprises a substrate for an enzyme present in wound fluid (par 0014). The degradable material comprises a material from the group of polylactide/polyglycolide copolymers, oxidized regenerated cellulose, and mixtures thereof (par 0024). Suitable therapeutic substances include antiseptics such as silver sulfadiazine, chlorhexidine, analgesics, steroids, antibiotics, growth factor, or mixtures thereof (par 0023). The device (1) provides sustained release of therapeutic agent into the wound fluid following the opening of the aperture (par 0048). The therapeutic substance is dispersed in or on a solid substrate (par 0011). The therapeutic substance is dispersed or encapsulated in a bioerodible substance (par 0048) selected from a group comprising proteins, polysaccharides, biodegradable synthetic polymers, glycosaminoglycans and mixtures thereof (par 048). The wound treatment device is packaged in a sterile microorganism-impermeable container (par 0062). Kirkwood fails to disclose the envelope having only one aperture. However, Heinecke discloses a wound treatment device (15) comprising a water impermeable (cols. 5-6, lines 60-7) envelope (19) having one aperture (18) in the envelope (19). Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the Kirkwood device to have only one aperture in the envelope, as taught by Heinecke, in order to force all the wound exudate into the wound dressing.

The applied reference has common inventors Breda Cullen and Derek Silock with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention

disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claims 1-2 and 5-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heinecke (US Patent 4,499,896) in view of Arnold (U.S. Patent 5,759,570). Heinecke discloses a wound treatment device (15) comprising a water impermeable (cols. 5-6, lines 60-7) envelope (19) having one aperture (18) in the envelope (19), wherein the aperture is between .01 and 1 sq-cm (col. 10, lines 31-32). The envelope (19) is formed of flexible sheet material because it has to expand and contract with the amount of fluid in the envelope (19). Heinecke fails to disclose a degradable material blocking the apertures, a therapeutic agent behind the degradable material and dispersed in a bioerodile substance, and a microorganism-impermeable container. Arnold discloses a wound dressing (1) comprising a water-impermeable envelope (col. 3, lines 49-54). The envelope contains a slow release therapeutic substance (col. 5, lines 4-6) that is released in the presence of wound fluid (col. 4, lines 22-25). The layer containing the therapeutic substance, dispersed on the wound contact layer, is degradable or bio-absorbable and contains collagen and glycosaminoglycans (col. 4, lines 52-53), which also provides a substrate for the enzymes to act upon. The wound dressing (1) also contains microbioside, such as chlorhexidine and maintains a sterile environment for the wound (col. 4, lines 10-14). The wound dressing (1) container is impermeable to micro-organisms (col. 3, lines 58-60). Therefore it would be obvious to

one of ordinary skill in the art at the time of the invention to modify the Heinecke device to have therapeutic agent and degradable material blocking the aperture, as taught by Arnold, in order to allow therapeutic agent to be released into the wound, which aids in the rapid healthy healing of the wound.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRANDON JACKSON whose telephone number is (571)272-3414. The examiner can normally be reached on Monday - Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571)272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brandon Jackson/
Examiner, Art Unit 3772

BLJ

/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772